10 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K063642

10.1 Submitter's Identification

DEC 1 3 2007

Fuji Dynamics Ltd.
Unit 1-3, 23/F., Laws Commercial Plaza,
788 Cheung Sha Wan Road,
Kowloon, Hong Kong
Tel: (852) 2786 4218
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Contact Person: Irene, Cheung Pui Lai
Date Prepared: 26th Nov 2007

10.2 Name of Device:

Proprietary Name: FD EMS

Common or Usual Name: EMS unit

Classification Name: Physical Medicine Device – Physical Medicine Therapeutic Device - Power Muscle Stimulator (21 CFR 890.5850)

Device Classification: Class II

10.3 Predicate Device Information:

The FD EMS is equivalent to the BMLS03-1 (K031427).

10.4 Device Description:

The FD EMS is a handheld battery powered EMS device, which is used for muscle stimulation. The device would generate electrical pulses and transmit it to the electrodes, which are attached to the skin of patient. Consequently, the electrical pulses would then pass through the skin to nerves of the muscle and cause the muscle to expand and contract.

FD EMS has two output channels and seven stimulation programs. The program mode is displayed on a LCD. The user can adjust the output intensity by 15 steps.

10.5 Intended Use:

Indications for use:

- Prevention or retardation of muscle disuse atrophy.
- Relaxation of muscle spasm.
- Muscle re-education.
- Maintaining or increasing range of motion.
- Increasing local blood circulation.
- Immediate post-surgical of calf muscle to prevent venous thrombosis.

10.6 Technological Comparison to Predicate Device:

The FD EMS has basic technological characteristics that are substantially equivalent to the predicate device. Both devices are battery powered and have adjustable output amplitudes. Both the legally marketed predicate device and FD EMS is a two channels device. The only significant technological difference between the two devices is that FD EMS possesses an open-circuit detection feature. It means that FD EMS could check the continuity between the output terminals, and avoid increment of output in the absence of load.

All units use "shrouded patient cable connectors" to comply with the FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables."

10.7 Non-clinical Testing:

Compliance to applicable voluntary standards includes EN 60601-1 and EN 60601-1-1 requirements.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

10.8 Clinical Testing

Not Applicable as there are no new or innovative aspects that have been introduced.

10.9 Conclusions:

The FD EMS has the same intended use and similar technical characteristics as the BMLS03-1 (K031427).

The information supplied in this 510(k) illustrates that the device do not pose any new

questions of safety and effectiveness. Therefore, the FD EMS is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

Fuji Dynamics Ltd.
% Ms. Irene Cheung Pui Lan
Unit 1-3, 23/F., Laws Commercial Plaza
788 Cheung Sha Wan Road
Kowloon, Hong Kong

Re: K063642
Trade/Device Name: FD EMS
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF
Dated: November 1, 2007
Received: November 29, 2007

Dear Ms. Irene Cheung Pui Lan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A—Indication For Use

510(k) Number (if known): K063642

Device Name: FD EMS

Indications for Use:

The FD EMS is a symmetrical biphasic neuromuscular electronic stimulator intended for medical purposes, which repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area. It is indicated for the following:

- Prevention or retardation of muscle disuse atrophy;
- Relaxation of muscle spasm;
- Muscle reeducation;
- Maintaining and increasing the range of motion;
- Increasing local blood circulation;
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

(Division Sign-Off)
Division of General, Restorat
and Neurological Devices

510(k) Number K063642

Prescription Use _X_ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)